

# Bayer HealthCare Pharmaceuticals



February 24, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852  
<http://www.fda.gov/dockets/ecomments>

Carol M. Moore  
Vice President  
Worldwide Regulatory Affairs  
Responsible Head / Agent

Re: Comments to Docket No. 2005N-0510  
Anti-Counterfeit Drug Initiative

Bayer HealthCare LLC, Hematology/Cardiology has reviewed the Federal Register notice regarding the Anti-Counterfeit Drug Initiative [Docket No. 2005N-0510] (Federal Register, Vol. 71, No. 7, published on January 11, 2006). Also, Bayer representatives attended the associated public workshop on February 8 and 9, 2006. Bayer supports initiatives that protect the patients using prescription medicines, including measures to deter counterfeit pharmaceuticals.

Bayer HealthCare LLC  
800 Dwight Way, P.O. Box 1986  
Berkeley, CA 94701-1986

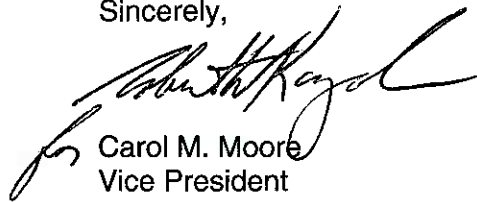
Phone: 510-705-5224  
Fax: 510-705-4712  
[carol.moore.b.@bayer.com](mailto:carol.moore.b.@bayer.com)

FDA is strongly encouraged to reconsider the format of the pedigree requirement of the Prescription Drug Marketing Act and its associated proposed regulations. The broad implications of industry adoption of radio-frequency identification (RFID) by 2007 appear to have been made prematurely. The technology of RFID and associated infrastructure is far from established and reliable in 2006. Radio-frequency identification is uncertain technology that clearly warrants the possible use of other tools, such as paper pedigrees or two-dimensional barcodes.

FDA is also strongly encouraged to establish universal requirements for the enforcement of the pedigree requirements. This suggestion is in harmony with the numerous presenters at the FDA Anti-Counterfeit Drug Initiative Workshop. By comparison, the state licensure of wholesale distributors has introduced more than 40 evolving systems of independent state regulations to enforce the same section of the Code of Federal Regulations (21CFR203.50). The administrative and business process burden to stay current with each state's requirements is increasing. The experience with the state wholesale distribution licenses and the suggestions from the workshop clearly indicate more uniform requirements are necessary.

Thank you for the opportunity to provide these comments on the Anti-Counterfeit Drug Initiative  
Docket No. 2005N-0510.

Sincerely,

A handwritten signature in black ink, appearing to read "Carol M. Moore", is written over the typed name.

Carol M. Moore  
Vice President  
Worldwide Regulatory Affairs  
Responsible Head/Agent

CMM/AA